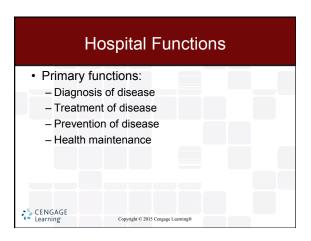


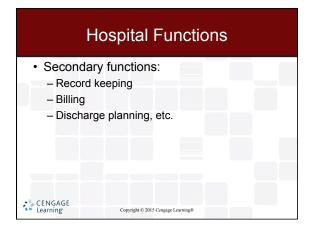


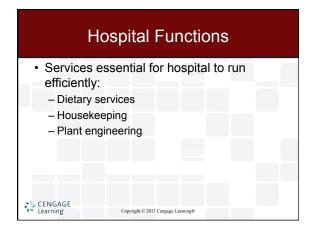
Types of Hospitals and Services Founded and funded by religious groups and charitable organizations Funded by public sector, health organizations, health insurance companies Hospitals now known as health systems or networks Profit, not-for-profit, government owned

















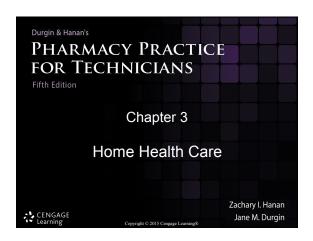


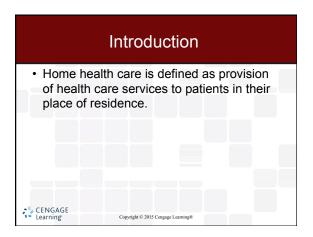
Hospital Pharmacy Technician First in military hospitals or clinics Clerical duties and courier functions Roles expanded to: Manufacturing and packaging products Distribution of medications Broad range of clinical, technical, and clerical tasks performed today CENGAGE Copyright © 2015 Congage Learning®



Structure and Organization of Hospital Pharmacy • Chief pharmacy officer - Part of a larger organization - Oversees committees • Pharmacy director - Directs overall operations







Home Health Care

- · First established in 1880s
 - Pharmaceutical services not yet included
- Enactment of Medicare in 1965 increased number of agencies
- · Medicare made services available to:
 - Elderly
 - Disabled younger Americans



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Home Health Care

- Pharmacy's role in health care progressed very little until 1983, when Medicare initiated reimbursement.
- Previously, medications not a covered benefit
 - Dramatic shift from in-patient to home care
- · Home infusion therapy began in 1970s.



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Home Health Care

- Technological advances, such as IVs, total parenteral feeding (TPN), and central venous catheters made home care more feasible.
 - Medicare willing to pay for TPN
 - · Cheaper than in-patient service
 - Many pharmacies opened and provided these infusion services to home care patients.



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Home Health Care

- U.S. costs are a higher percentage of the economy than anywhere else in the world.
- Employers, government, and insurance providers seek ways to manage costs more effectively.
- Number of patients grows as population ages.



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Home Health Care

- Competition among pharmacies will grow.
 - Home care providers may contract with managed care networks.
- Home care will become predominant setting for provision of drug therapies and pharmacy practice.



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Home Health Care Services and Providers

- Encompasses wide range of services, including:
 - Nursing
 - Dietitians
 - Social work
 - Physical and occupational therapy
 - Dental

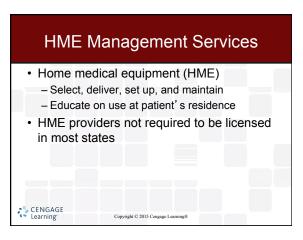


Home Health Care Services and **Providers** · Home health agencies - Public (government) - Nonprofit - Proprietary - Hospital based CENGAGE Learning Copyright © 2015 Cengage Learning®

Personal Care and Support Services · Nonprofessional services to patients in their place of residence - Homemaking, food prep, and personal care - Performed by home health aides · Also called homemakers or personal care attendants · Second most common CENGAGE Learning

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HME Management Services · Many pharmacies participate · When respiratory services needed, pharmacies must be involved to either: - Provide services - Contract with HME provider CENGAGE Learning Copyright © 2015 Cengage Learning®

Home Pharmacy Services No clear definition since overlap with retail and community pharmacy practice · Homebound or home care patient · Medications delivered or shipped to patient's residence · Pharmacy responsible for monitoring patient's medication on ongoing basis CENGAGE Learning Copyright © 2015 Cengage Learning®

Role of Pharmacy in Home Health Care • Home infusion therapy - Medical therapy in patient's residence involving prolonged injection of pharmaceutical products • Infusion therapy is 90 percent of home pharmacy service.

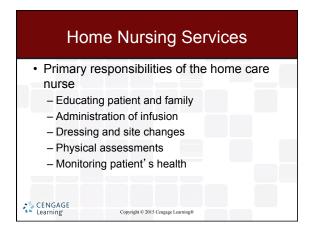


Pharmacy Services Compounding and dispensing IV solutions into ready-to-administer forms Preparation less frequent For example, one month from preparation to administration Script labels must conform to state pharmacy laws.



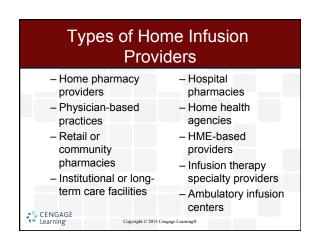
Pharmacy Services • Home infusion pharmacies — Provide nursing supplies, catheter supplies, and access devices — Must comply with U.S. Pharmacopeia (USP)











Physician-Based Practices Most common practice model Oncology and infectious disease practices Usually an ambulatory infusion center or physician office Nurses usually prepare the medications Copyright © 2015 Congage Learning®



Institutional or LTC Pharmacies

- · Drug distribution services
- · Primarily oral medications but do provide some infusion services
- · Home infusion is a low percentage of the overall business



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Hospital Pharmacies

- · Home infusion provided by department of pharmacy or outpatient services
- Usually provide equipment and delivery services
- · May be a separate satellite office



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Home Health Agencies

- · Pharmacy supplements home health services
- · Pharmacy may serve multiple branches of the agency



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HME-Based Provider

- Supplies respiratory therapy medications that are needed for the home medical equipment and clinical respiratory needs of their patients
- · Similar to retail in operation



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Infusion Therapy Specialty Provider

- · Home infusion is the sole business.
- · Pharmacy plays dominant role.
- Services center around infusion equipment and delivery.



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Ambulatory Infusion Centers

- Usually associated with a physician office
- · Run and managed by nurses
- · Licensed as pharmacies
- · Pharmacist or pharmacy technician prepares medications.

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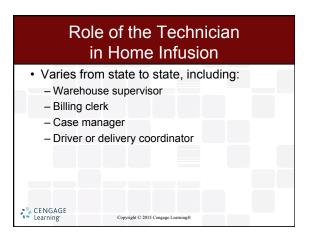
Preparing and Dispensing Medications for Home Care Requires specialized knowledge and skills Must be familiar with differences in pharmacy law and regulations Compounding practices must adhere to USP 797.

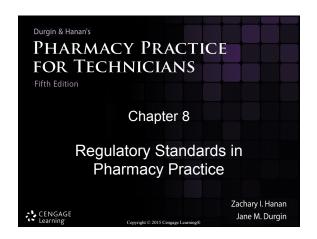
Preparing and Dispensing Medications for Home Care • Timing of preparation and dispensing is critical to delivery of stable, sterile product

Role of the Technician in Home Infusion • Vary from state to state, including: - Preparer of sterile products - Equipment management technician - Patient service representative - Purchasing agent or manager

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Statutes, Rules, Regulations, and Quasi-Legal Standards

- · Quasi-Legal standards
 - Quasi means "similar to"
 - Established by quasi-governmental or private organizations, such as professional pharmacy organizations
 - Are recognized by the federal government and many state governments and can form the basis of laws and regulations

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Federal versus State and Local Laws

- Practice of pharmacy is basically regulated by state law and is generally under the auspices of the state board of pharmacy.
- A federal law or regulation that pertains to your practice; it may take precedence over state or local law.
- When two or more laws exist in an area, generally the best course is to follow the most stringent law or regulation.



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State Regulation of Pharmacy Practice

- · State boards of pharmacy
 - Ensure that the public is well served professionally by pharmacists, that the drugs distributed and dispensed by the pharmacy within each state meet that state's standards for purity and potency, and that dispensed medications are properly labeled by the pharmacist for the patient's use.



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Food and Drug Administration (FDA)

 Responsible for assuring that the products under its jurisdiction are safe and effective for their intended use



Laws the FDA Enforces

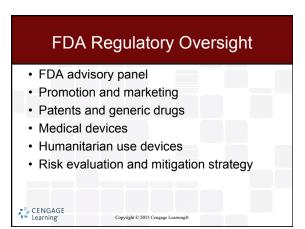
- Pure Food and Drug Act of 1906
 - Prohibited adulteration and misbranding of foods and drugs in interstate commerce
- Federal FDCA of 1938
 - Required new drugs to be proven safe before marketing

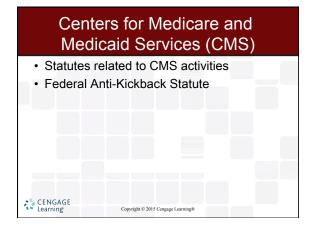


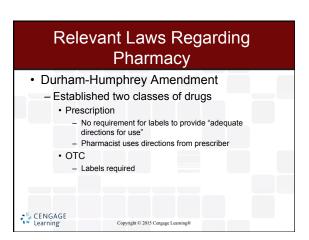












Relevant Laws Regarding Pharmacy

- · Medical Device Amendment
 - Provides for more extensive regulation regarding the safety and efficacy of medical devices
- Orphan Drug Act
 - Provides various tax and licensing incentives to drug manufacturers to develop and market orphan drugs for the diagnosis, treatment, or prevention of rare diseases or conditions

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Relevant Laws Regarding Pharmacy

- FDA Modernization Act of 1997 (FDAMA)
 - Streamlined regulatory procedures by encouraging manufacturers to:
 - · Research new uses of drugs
 - · Conduct pediatric studies of drugs

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Controlled Substances Act (CSA) of 1970

- Important federal law regulating manufacture, distribution, and sale of drugs with potential for abuse and dependence
- · Classifications:
 - Schedule I
 - No current approved medical use in the United States
 - · Abuse potential

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CSA of 1970

- · Classifications:
 - Schedule II
 - · High abuse and dependency potential
 - Required to be affixed with orange label and caution statement
 - Schedule III
 - · Less abuse and dependency potential

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CSA of 1970

- · Classifications:
 - Schedule IV
 - Minimal abuse and dependency potential
 - Schedule V
 - · Contain limited quantities of narcotics

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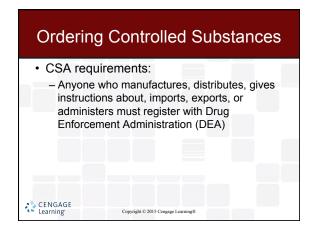
Maintenance of Controlled Substances

- Some hospitals and health care facilities authorized to purchase, possess, and use controlled substances
- Must keep many records, including:
 - Order from person authorized to prescribe
 - Separate record at main point of supply for controlled substance

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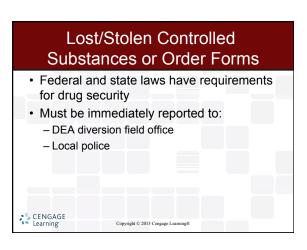
Maintenance of Controlled Substances • Must keep many records, including: - Record of authorized requisitions for such drugs - Documentation of each substock (amount on nursing unit) - Entry on patient's medical administration record (MAR) upon each administration



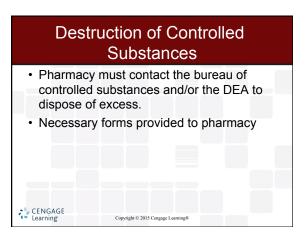


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Issuing Prescriptions

- Only issued by authorized, licensed individual
 - Licensed in practicing state
- Employee (nurse or secretary) can communicate prescription issued from practitioner to pharmacist
- · Only pharmacist can fill prescription



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Dispensing Controlled Substances

- Only if state law allows, pharmacy technician can dispense under supervision of pharmacist
- Prescriptions must have name of prescriber and signature of physician



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Dispensing Controlled Substances

 Pharmacist may dispense on oral authorization, but must follow series of steps in accordance with law.



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Record-keeping Requirements

- All records must be kept for at least two years at place of registration.
- · State law may require longer.
 - For example, New York requires 5 years
 - Must adhere to higher standard



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Federal Hazardous Substances Act

- Requires that certain hazardous household products ("hazardous substances") bear cautionary labeling to alert consumers to the potential hazards that those products present and to inform them of the measures they need to protect themselves from those hazards
- · Consumer Product Safety Commission



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Poison Prevention Packaging Act

- An amendment to the Federal Hazardous Substances Act
- Regulates certain substances defined as "household substances"
- Requires packaging for consumer use that will make it significantly difficult for children under the age of 5 to open, but not difficult for adults to open within a reasonable time



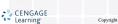
Occupational and Safety Act (OSHA)

- · OSHA established
- Created to decrease hazards in the workplace, to maintain a reporting system for monitoring job-related injuries and illnesses, and to develop mandatory job safety and health standards



Occupational and Safety Act

- Established Hazard Communication Standard (HCS)
 - Written hazard communication plan
 - Protection from air contaminants
 - Appropriate storage flammable and combustible materials
 - Provision of portable fire extinguishers



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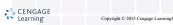
Omnibus Budget Reconciliation Act (OBRA) of 1990

- Three mandated provisions that affect pharmacy:
 - Drug manufacturers required to provide lowest prices to Medicaid patients
 - Drug use review
 - Patient counseling



Omnibus Budget Reconciliation Act (OBRA) of 1990

- Virtually every state has implemented regulations for all patients similar to those in OBRA
- Ensures higher level of patient care and professional service



Health Insurance Portability and Accountability Act (HIPAA)

- Aimed at improving efficiency and effectiveness of American health care system by adopting national standards for electronic health care transactions
- Requires protection of personal health care information



Health Insurance Portability and Accountability Act (HIPAA)

- Title I
 - Insurance reform protects health insurance coverage for workers and their families when they lose their job
- Title II
 - Simplify administrative functions by standardizing health care transactions



Regulatory Standards for Marketed Drugs · Patient package inserts - Necessary labeling of medication important for both professional and patient information - Required for safe and appropriate prescription use of medication Educate patient on medication

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Regulatory Standards for Marketed Drugs Labeling - Prescription drugs labeled for health care professional rather than patient - Unit dose packaging used when single dosage of drug is packed for administration - Regulated by FDA CENGAGE Learning

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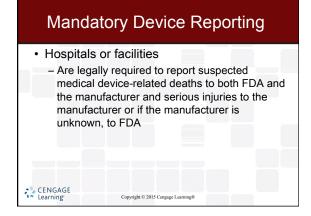
Regulatory Standards for **Marketed Drugs** National drug code (NDC) - Required on all OTC and prescription drugs - Ten numbers · First five digits identify manufacturer · Last five digits identify drug name, package size, and type of drug - FDA mandates pharmaceutical bar coding to help reduce medication errors. CENGAGE Learning Copyright © 2015 Cengage Learning®



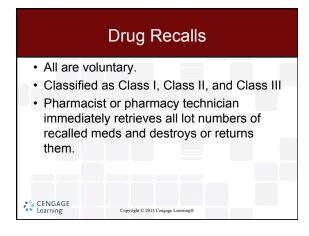
Orange Book Resource for pharmacists to research drug equivalents to generic forms of the drugs · A two-letter coding system for drug products with therapeutic equivalence is used. CENGAGE Learning Copyright © 2015 Cengage Learning®



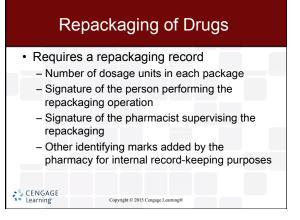












Product Tampering

- Regulations are in place that require OTC, prescription drugs, and medical devices be placed in tamper-proof packaging.
- If the packaging is damaged, it indicates the product was tampered with.

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The U.S. Pharmacopeia and National Formulary

- · Official compendium of drugs in use
- · Includes monographs of the drugs
- Provides guidelines for compounding sterile preparations

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Medicare

- Provides federal health insurance for those older than 65 years of age and for certain disabled individuals, regardless of age
 - Part A hospitalization
 - Part B diagnostic services
 - Part D prescription drugs

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Long-Term Care Facility Regulation

- · Received federal funding
- · Need to comply with CMS regulations
- · Surveyed annually for compliance

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Tax-Free Alcohol

- Tax-free ethyl alcohol will be used only for specific purposes:
 - It will not be used for beverage purposes.
 - It is not for resale.
 - It is used in accordance with uses stated on the alcohol permit.
- · Regulated by the ATF

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The Joint Commission

- Formed in 1951
- Mission is to address quality of patient care and safety
- Establishes optimal standards for health care providers

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The Joint Commission • Evaluates organizations for compliance with standards through unannounced survey • Accredits organizations

